

Application No. 09/614,669
Amendment Dated: April 11, 2003
Response to Office Action Dated February 19, 2003

5

REMARKS/ARGUMENTS

Claims 1, 5-8, 10, 11, and 13-20 are pending in the Application. Claims 1, 5-8, 10, 11, and 13-20 stand rejected. Claims 1, 5-8, 10, 11, and 13-20 stand rejected under 35 USC § 112, second paragraph. Claims 1 and 6-8 stand rejected under 35 USC § 102(e).

Claim Amendments

Claims 1 and 8 have been amended to:

- 1) provide antecedent basis for the term "response";
- 2) incorporate the matter of Claim 7, further defining the visual measurement as using a predefined scale;
- 3) delete an exemplary embodiment (Support for this amendment can be found in Claim 7 as originally filed. Exemplary predefined scales for visual measurement can be found at page 5, lines 5-8 and at page 21, lines 1-21.); and
- 4) delineate specific physical challenges (Support for this amendment can be found at page 5, line 32-page 6, line 6 and at page 8, lines 20-22.).

Claim 7 has been amended to delete reference to visual measurement so as to only recite "TEWL measurement" so as to further limit Claim 1 as amended.

The preamble of Claim 8 has been amended to more clearly describe the claimed study as using the enhanced and/or prolonged responses. Support for this amendment can be found at page 8, lines 3-9. As described therein, particularly at lines 7-9, the claimed studies are intended to understand matters other than enhancing and/or prolonging responses as was described by Claim 8 before the amendment.

Claim 16 has been amended to delete recitation of cell cultures.

Rejections Under 35 USC § 112, Second Paragraph

Claims 1, 5-8, 10, 11, and 13-20 stand rejected under 35 USC § 112, second paragraph as being indefinite. Specifically:

- In Claims 1 and 20 (The Applicants assume that the Examiner intended to direct them to Claims 1 and 8.) the recitation of "the condition" is indefinite because an exemplary embodiment is recited in parentheses. MPEP § 2173.05(d) is used as an authority.

Application No. 09/614,669
Amendment Dated: April 11, 2003
Response to Office Action Dated February 19, 2003

6

- The Office Action understands the term "condition" to be broader than the term "response" making recitation of "condition" in the concluding step of each claim unclear because previous steps refer to assessing various "responses".
- The last line recitation in Claim 1 of comparing plural test sites is unclear when previous lines of the claim refer to only one test site and one response.

The Applicants respectfully direct the Examiner to the amendment to Claims 1 and 8 and note:

- Claims 1 and 8 have been amended to delete the recitation of an exemplary embodiment. The Applicants submit that the matter deleted from Claims 1 and 8 moots the indefiniteness associated with respect to the terms "test sites" and "comparing".
- Claims 1 and 8 have been amended to provide antecedent basis for the term "response". The Applicants submit that these amendments address the indefiniteness issues raised by the Office Action with respect to the term "response" because the amended claims now clearly recite that a test site on a responsive system is subjected to primary and secondary challenges and then the response to the challenges is assessed.
- Claim 8 has been amended to clarify the various responses that can be measured. As described therein:
 - A test site is selected.
 - One or more controls are selected.
 - A primary challenge is applied to the test site and a primary challenge response is assessed.
 - A secondary challenge is applied to the test site, after primary challenge response assessment.
 - At least one secondary challenge response is assessed after secondary challenge application. Additional secondary challenge response assessments can be made at various times after the initial secondary challenge response assessment.
 - If controls are selected, control assessments are made at about the same times as the primary and secondary challenge assessments are made.

Application No. 09/614,669
Amendment Dated: April 11, 2003
Response to Office Action Dated February 19, 2003

7

- Depending on the assessment results, conclusions are drawn.

The Applicants submit that the amendment to Claim 8 addresses the indefiniteness issues with respect to the assessment steps and with respect to the various responses.

- Claim 16 has been amended to delete the reference to cell cultures. The Applicants respectfully submit that this amendment addresses the issue raised by the Office Action with respect to Claims 16-20.

Given the amendments to Claims 1, 8 and 16 and the dependency of Claims 5-7, 10, 11, and 13-20 from one of Claim 1 or Claim 8, the Applicants respectfully submit that the rejections of Claims 1, 5-8, 10, 11, and 13-20 under 35 USC § 112, second paragraph have been overcome and request the withdrawal thereof.

Rejections Under 35 USC § 102(e)

Rejection Over Kapadia, et al. (US 5,935,581)

Claims 1, 6 and 7 stand rejected under 35 USC § 102(e) as being anticipated by Kapadia, et al. (US 5,935,581). Specifically:

- The Office Action notes that Kapadia, et al. does not anticipate Claim 8 or any of its dependents.
- Paper No. 10 asserts that the Kapadia reference uses the skin of mice as a responsive system where the "response" is formation of papillomas/epidermal tumors. Paper No. 10 further asserts that application of a known tumor initiator (DBMA) corresponds to the presently claimed primary challenge and that the twice weekly treatment with ultraviolet B radiation for a corresponds to the presently claimed secondary challenge. Paper No. 10 goes on to assert that throughout the period of UV treatment the mice are assessed for the appearance of papillomas/epidermal tumors corresponding to the claimed assessment step.
- The present Office Action asserts that treatment with a food colorant corresponds to the post-challenge intervention described in Claim 6.
- Kapadia's determination of the incidence of papillomas corresponds to the visual assessment described in Claim 7.

The Applicants respectfully direct the Examiner to the amendments to Claims 1 and 7 and note:

Application No. 09/614,669
Amendment Dated: April 11, 2003
Response to Office Action Dated February 19, 2003

8

- The amendment to Claim 1 removes the Kapadia reference as an anticipatory reference. The Applicants respectfully submit that exposure to high intensity UVB light bears no relation to any of the physical secondary challenges that are described in Claim 1 as amended.
- Claim 7 as amended is novel over the Kapadia reference even without the amendment to Claim 1 because there is nothing therein that would teach or suggest an assessment using TEWL.

Given that the Applicants have shown that Claim 1 as amended is novel over the Kapadia reference and given the dependency of Claim 6 from Claim 1 (a dependent claim having all the limitations of the base claim) and given further the novelty of Claim 7 both due to the dependency from Claim 1 as amended and due to the amendment so as to limit Claim 7 to a recitation of only TEWL, the Applicants respectfully request that the rejection, under 35 USC § 102(e), of these claims over the Kapadia reference be reconsidered and withdrawn.

Rejection Over Fruehauf, et al. (US 6,008,007)

Claims 1 and 8 stand rejected under 35 USC § 102(e) as being anticipated by Fruehauf, et al. (US 6,008,007). Specifically, the Office Action asserts that Fruehauf's sensitizing/chemotherapeutic drug corresponds to the claimed primary challenge, Fruehauf's radiation corresponds to the secondary challenge, Fruehauf's wells correspond to a test site (including the claimed controls) and Fruehauf's measurement of incorporated thymidine corresponds to the claimed assessment.

The Applicants again respectfully direct the Examiner to the amendment to Claims 1 and 8 and submit:

- There is nothing in the Fruehauf reference that anticipates the listing of physical secondary challenges as described in the amended claims.
- Neither reference teaches or discloses either assessment by visual evaluation using a predefined scale or TEWL as described in the amended claims.

Since, in order to anticipate, a reference must teach or disclose all of the limitations of a claim, the Applicants submit that the Fruehauf reference fails to anticipate Claims 1 and 8 as amended. Therefore, the Applicants respectfully request reconsideration of the rejection of Claims 1 and 8 under 35 USC § 102(e) and that it be withdrawn.

Application No. 09/614,669
Amendment Dated: April 11, 2003
Response to Office Action Dated February 19, 2003

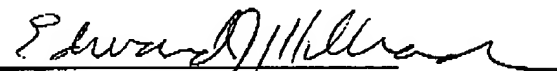
9

SUMMARY

All of the objections and rejections in the Office Action have been discussed as have the distinctions between the cited references and the claimed invention. No new matter has been added by the Amendment. In light of the discussions contained herein, the Applicants respectfully request reconsideration of the rejections and their withdrawal, and that all of the claims be allowed. Issuance of a Notice of Allowance at an early date is earnestly solicited.

Respectfully submitted,

For: Tepper et al.



Edward J. Milbrada
Agent for Applicants
Reg. No. 40,090
(513) 626-1167

Date: April 10, 2003

Customer No. 27752